*OMB No.:* 0970–0360.

*Description:* The Office of Adolescent Health (OAH), Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS), is overseeing and coordinating adolescent pregnancy prevention evaluation efforts as part of the Teen Pregnancy Prevention Initiative. OAH is working collaboratively with the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Centers for Disease Control and Prevention (CDC), and the Administration for Children and Families (ACF) on adolescent pregnancy prevention evaluation activities.

The Evaluation of Adolescent Pregnancy Prevention Approaches (PPA) is one of these efforts. PPA is a random assignment evaluation which will expand available evidence on effective ways to reduce teen pregnancy. The evaluation will document and test a range of pregnancy prevention approaches in up to eight program sites. The findings from the evaluation will be of interest to the general public, to policy-makers, and to organizations interested in teen pregnancy prevention.

OAH and ACF are proposing baseline data collection activity as part of the PPA evaluation. Baseline data collection instruments were already approved on July 26, 2010. The project has worked in recent months to secure grantees as evaluation sites, and as part of this effort the project has undertaken making revisions to the baseline instrument with each site. These revisions were undertaken because each site has unique features (*e.g.* target population; curriculum; objectives) and the baseline instruments were tailored to take these features into account. OAH and ACF are now requesting emergency clearance to collect data using site-specific instruments.

Respondents will be asked to answer carefully selected questions about demographics and risk and protective factors related to teen pregnancy. Information from this data collection will be used to perform meaningful analysis to determine significant program effects.

*Respondents:* The survey data will be collected through private, self-administered questionnaires completed by study participants, *i.e.* adolescents assigned to a select school or community teen pregnancy prevention program or a control group. Surveys will be distributed and collected by trained professional staff.

ANNUAL BURDEN ESTIMATES

| Site/program (and name of baseline instrument) | Annualized no. of respondents | No. of responses per respondent | Average burden hours per response | Total burden hours (annual) |
|---|---|---|---|---|
| Children's Hospital of Los Angeles/Project AIM | 467 | 1 | .7 | 327 |
| Oklahoma Institute of Child Advocacy/Power Through Choices | 360 | 1 | .6 | 216 |
| Engender Health/Gender Matters | 375 | 1 | .6 | 225 |
| Ohio Health/T.O.P.P. | 200 | 1 | .7 | 140 |
| Live the Life Ministries/WAIT Training | 533 | 1 | .7 | 373 |
| Princeton Center for Leadership Training (PCLT)/TeenPEP | 533 | 1 | .6 | 320 |
| Total | 2468 | | | 1601 |

*Estimated Total Annual Burden Hours:* 1601.

Additional Information:

ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by July 1, 2011. A copy of this information collection, with applicable supporting documentation, may be obtained by e-mailing *OPREinfocollection@acf.hhs.gov.*

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, *Attn:* OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503, Fax (202) 395–6974.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2011–16290 Filed 6–28–11; 8:45 am]

**BILLING CODE 4150–30–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0439]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Recall Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements on FDA recalls.

**DATES:** Submit either electronic or written comments on the collection of information by August 29, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr. PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**FDA Recall Regulations—21 CFR Part 7 (OMB Control Number 0910–0249)—Extension**

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) and part 7 (21 CFR part 7), subpart C set forth the recall regulations (guidelines) and provide guidance to manufacturers on recall responsibilities. The guidelines apply to all FDA regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; biological products intended for human use; and tobacco). These responsibilities include development of a recall strategy that requires time by the firm to determine the actions or procedures required to manage the recall (§ 7.42); providing FDA with complete details of the recall including reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, a copy of any recall communication(s), and a contact official (§ 7.46); notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (§ 7.49); and submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things, evaluation return reply cards, effectiveness checks and product returns (§ 7.53); and providing the opportunity for a firm to request in writing that FDA terminate the recall (§ 7.55(b)).

A search of the FDA database was performed to determine the number of recalls, and terminations that took place during fiscal years 2008 to 2010. The resulting number of total recalls (9,303) and terminations (2,858) from this database search were then averaged over the 3 years, and the resulting per year average of recalls (3,101) and terminations (953) are used in estimating the current annual reporting burden for this report. FDA estimates the total annual industry burden to collect and provide the previous information to be 443,820 burden hours.

The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply with the voluntary reporting requirements of FDA's recall regulations. Recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Recall strategy (§ 7.42) | 3,101 | 1 | 3,101 | 20 | 62,020 |
| Firm initiated recall and recall communications (§§ 7.46 and 7.49) | 3,101 | 1 | 3,101 | 30 | 93,030 |
| Recall status reports and followup (§ 7.53) | 2,148 | 13 | 27,924 | 10 | 279,240 |
| Termination of a recall (§ 7.55(b)) | 953 | 1 | 953 | 10 | 9,530 |
| Total | | | | | 443,820 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The annual reporting burdens are explained as follows:

**I. Total Annual Reporting**

*A. Recall Strategy*

Request firms develop a recall strategy including provision for public warnings and effectiveness checks. Under this portion of the collection of information, the Agency estimates it will receive 3,101 responses annually based on the average number of recalls over the last 3 fiscal years.

*B. Firm Initiated Recall and Recall Communications*

Request firms voluntarily remove or correct foods and drugs (human or animal), cosmetics, medical devices, biologics, and tobacco to immediately notify the appropriate FDA district office of such actions. The firm is to provide complete details of the recall reason, risk evaluation, quantity produced, distribution information, firms' recall strategy and a contact official as well as requires firms to notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under these portions of the collection of information, the Agency estimates it will receive 3,101 responses annually based on the average number of recalls over the last 3 fiscal years.

*C. Recall Status Reports*

Request that recalling firms provide periodic status reports so FDA can ascertain the progress of the recall. This request only applies to firms with active recalls, and is estimated to be reported every 2 to 4 weeks. This collection of information will generate approximately 27,924 responses annually, based on the average number of recalls over the last 3 fiscal years (3,101), less the average number of terminations over the last 3

fiscal years (953), multiplied by the conservative frequency of reporting per year (13).

*D. Termination of a Recall*

Provide the firms an opportunity to request in writing that FDA end the recall. The Agency estimates it will receive 953 responses annually based on the average number of terminations over the past 3 fiscal years.

**II. Hours per Response Estimates**

FDA has no information which would allow it to make a calculated estimate on the hours per response burden to FDA regulated firms to conduct recalls. Variables in the type of products, the quantity and level of distribution and the various circumstances of recall notifications could cause the hours per response to vary significantly. The best guesstimate of average burden hours per response from previous information collection request reports are utilized again for the current estimates on burden hours per response.

Dated: June 23, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–16252 Filed 6–28–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0502]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; National Consumer Surveys on Understanding the Risks and Benefits of FDA—Regulated Medical Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by July 29, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''National Consumer Surveys on Understanding the Risks and Benefits of FDA–Regulated Medical Products.'' Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794.

*JonnaLynn.Capezzuto@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**National Consumer Surveys on Understanding the Risks and Benefits of FDA–Regulated Medical Products—(OMB Control Number 0910–NEW)**

Risks and benefits are inherent in all FDA-regulated medical products, including drugs, biologics, and medical devices (*e.g.,* pacemakers, implantable cardiac defibrillators, contact lenses, infusion pumps). FDA plays a critical oversight role in managing and preventing injuries and deaths related to medical product use. However, the users of FDA-regulated products are ultimately the ones who determine which products are used and how they are potentially misused. For this reason, it is critical that the public understand the risks and benefits of FDA-regulated medical products to a degree that allows them to make rational decisions about product use.

FDA's responsibility includes communicating about medical products. This encompasses communications that FDA generates and those it oversees through regulation of product manufacturers' and distributors' communications. Activities include, but are not limited to, recall notices, warnings, public health advisories and notifications, press releases, and information made available on its Web site. FDA also regulates communications drafted and disseminated by manufacturers and distributors of many medical products, including all the communications (advertising and labeling) about prescription drugs, biologics, and restricted medical devices, and a subset of communications (omitting advertising) about nonprescription drugs and other medical devices. In order to conduct educational and public information programs relating to these responsibilities, as authorized by section 1003(d)(2)(D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), it is beneficial for FDA to conduct research and studies relating to health information as authorized by section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)).

In conducting such research, FDA will employ nationally representative surveys of consumers to assess whether the information being disseminated by both the Agency and the entities it regulates is appropriately reaching targeted audiences in an understandable fashion. Specifically, the surveys will assess public understanding about the benefits and risks of medical products and FDA's role in regulating these products. The surveys will assess behaviors and beliefs related to the use of medical products, when consumers desire emerging risk information, the likelihood of reporting serious side effects that might be associated with medical product use, perceptions of the credibility of FDA and other potential sources of risk and benefit information, and satisfaction with FDA's communications-related performance.

Parallel surveys of 1,500 noninstitutionalized U.S. adults will be administered. One survey of 1,500 subjects will be a telephone survey, and the second survey of another 1,500 subjects will be conducted with members from an Internet panel. Both survey samples will be constructed to be representative of the U.S. population, and both will take approximately 15 minutes to administer. Results from each survey will be compared to provide insight into the best methodology for future studies.

The information collected will be used by FDA in the development of more effective risk communication strategies and messages. The surveys will provide FDA insight as to how well the public understands and incorporates risk/benefit information into their belief structures, and how well the public understands the context within which FDA makes decisions on medical product recalls and warnings. Using this information, the Agency will more effectively design messages and select formats and distribution channels that have the greatest potential to influence the target audience's attitudes and behavior in a favorable way. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; *Type of Respondents:* Members of the public.

In the **Federal Register** of October 5, 2010 (75 FR 61490), FDA published a 60-day notice requesting public comment on the proposed collection of